

REMARKS

Applicant respectfully requests reconsideration. Claims 15-65 were previously pending in this application. By this amendment, Applicant is canceling claims 18, 22, 27, 32, 33, 35, 44, 48 and 54-57 without prejudice or disclaimer. Claims 15, 19, 20, 23, 24, 28, 34, 36, 38-43, 45, 47, 49, 58, 62 and 64 have been amended. Claims 15, 20, 24, 34, 43, 58 and 62 were amended to recite that the magnetic particle is coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Support for this amendment can be found throughout the specification, at least on page 14, lines 9-10, and in claims 18, 22, 27, 32 and 48 as previously pending. Claims 38-40, 49 and 64 were amended to clarify the claim language. Claims 19, 23, 28, 36, 41, 42, 45, 47 and 49 were amended to modify claim dependencies.

As a result, claims 15-17, 19-21, 23-26, 28-31, 34, 36-43, 45-47, 49-53 and 58-65 are currently pending with claims 15, 20, 24, 34, 43, 58 and 62 being independent claims. Applicant reserves the right to pursue the subject matter of the claims as previously pending, or as originally filed, in one or more continuing applications. No new matter has been added.

Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 43-65 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserts that the terms “sufficient” in claim 43 and “effective” in claims 58 and 62 render these claims indefinite. Applicant respectfully disagrees.

The standard for definiteness of a claim term such as “sufficient” or “effective” is “whether or not one skilled in the art could determine specific values for the amount based on the disclosure. *See In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975).” MPEP § 2173.05(c). The specification provides sufficient disclosure to allow one skilled in the art to determine specific values for “sufficient” or “effective” amounts or durations recited in the pending claims.

The specification discloses that, as would be understood by one skilled in the art, the “administration route, dosage or number of administrations” of magnetic cells can vary depending on “symptoms, type and severity of the disease, age, heart, liver and kidney functions and the like.” (Page 11, lines 20-23). An example of dosage guidelines for administration of magnetic particles is provided on page 11, line 23 to page 12, line 4. Moreover, the specification discloses that magnetic particles can be “retained for a long time at a disease site,” and further defines this duration to mean “long enough for its functions to be performed.” (Page 15, lines 21-23). An example of duration guidelines for magnetic particles is provided on page 15, lines 23-24. Thus, based on the disclosure in the specification, one skilled in the art would be able to readily determine when values for the amounts and durations of administration of magnetic particles achieved the result recited in the claims.

Furthermore, an “effective amount” of a compound is definite, even if the intended utility is not recited in the claims, if the supporting disclosure “provided guidelines as to the *intended utilities*” (Emphasis added). See *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), MPEP § 2173.05(c).

The *intended utilities* of the “sufficient” or “effective” amounts or durations recited in the pending claims are recited in the claim language itself. Claim 43 is directed to a method of inducing tissue repair in a subject by administering a magnetic cell into the subject and applying a magnetic field in the subject “in an amount or duration *sufficient to induce tissue repair*.” Claim 58 is directed to a method for treating a tumor in a subject by administering a magnetic cell to a subject and applying a magnetic field to the subject “in an amount and duration *effective to treat the tumor*.” Claim 62 is directed to a method of treating dementia by administering a magnetic cell to a subject and applying a magnetic field to the subject “in an amount and duration *effective to treat the dementia*.” Thus, the intended utilities of the “sufficient” or “effective” amounts or durations recited in the pending claims would be apparent to one of ordinary skill in the art from the claim language, rendering these claim terms definite.

Therefore, the pending claims particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 34, 35, 43, 44, 46 and 47 under 35 U.S.C. § 102(b) as allegedly anticipated by Ludwig et al. (US 2003/0082148).

Applicant respectfully traverses the rejection. A claim is anticipated only if each and every element as set forth in the claim is found in the prior art reference. MPEP § 2131. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claims 34 and 43 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claims 35 and 44 have been cancelled herein, rendering rejection of these claims moot. Claims 46 and 47 depend from claim 43 and incorporate the features of that claim.

Ludwig et al. does not disclose coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, Ludwig et al. does not teach all of the elements of the claimed invention and hence does not anticipate the claimed invention. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

A. The Examiner rejected claims 41 and 42 under 35 U.S.C. § 103(a) as allegedly obvious over Ludwig et al. (US 2003/0082148).

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claim 34 to

recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claims 41 and 42 depend from claim 34 and incorporate the features of this claim.

Ludwig et al. does not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, Ludwig et al. does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

B. The Examiner rejected claims 15, 16, 18, 20-25, 27, 29, 30, 32, 36, 45, 48 and 49 under 35 U.S.C. § 103(a) as allegedly obvious over Ludwig et al. (US 2003/0082148) in view of Stickel et al. (1988) *J. Cell Biology* 107:1231-1239.

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claims 15, 20, 24, 34 and 43 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claims 18, 22, 27, 32 and 48 have been cancelled herein, rendering the rejection of these claims moot. Claims 16, 21, 23, 25, 29, 30, 36, 45 and 49 depend from claims 15, 20, 24, 34 and 43 and incorporate the features of these claims.

The Examiner acknowledges on page 6 of the Office Action that the combined disclosure of the cited references is “silent as to the amount of peptide coating the magnetic particle.” However, the Examiner asserts that such a difference in concentration does not support patentability “unless there is evidence indicating that such concentration is critical.” (Office Action, Page 6). The specification does, in fact, indicate that the concentration of peptide coated on the magnetic particle

is critical. Page 14, lines 10-13 states “If too much peptide is coated on the magnetic bead, the final magnetic cells end up adhering to each other, impeding movement to the disease site which is the target. If too little is coated, the properties of the magnetic cell itself cannot be achieved.” Because “there is evidence indicating such concentration is critical,” the optimized concentrations render the claimed invention non-obvious. See MPEP § 2144.05 III (“Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range.”).

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle as recited in the pending claims. Furthermore, one of ordinary skill in the art would not have had any reason to modify the teachings of the cited references to arrive at this critical aspect of the claimed invention. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

In light of the above remarks, Applicant needs not further address the Examiner’s characterization of claims 23, 29 and 49 on pages 6-7 of the Office Action. Accordingly, withdrawal of this rejection is respectfully requested.

C. The Examiner rejected claims 17, 19, 26, 28, 31 and 33 under 35 U.S.C. § 103(a) as allegedly obvious over Ludwig et al. (US 2003/0082148) in view of Stickel et al. (1988) *J. Cell Biology* 107:1231-1239 and further in view of Chen et al. (US 5,921,244).

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claims 15 and 24 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claim 33 has been cancelled herein, rendering rejection of this claim moot. Claims 17, 19, 26, 28 and 31 depend from claims 15 and 24 and incorporate the features of these claims.

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 μ g of the peptide to 1 mg of the magnetic particle as recited in the pending claims. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

D. The Examiner rejected claims 37-40 and 50-57 under 35 U.S.C. § 103(a) as allegedly obvious over Ludwig et al. (US 2003/0082148) in view of Kubo et al. (2000) *J. Oncology* 17:309-315.

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claims 34 and 43 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 μ g of the peptide to 1 mg of the magnetic particle. Claims 54-57 have been cancelled herein, rendering rejection of these claims moot. Claims 37-40 and 50-53 depend from claims 34 and 43 and incorporate the features of these claims.

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 μ g of the peptide to 1 mg of the magnetic particle as recited in the pending claims. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

E. The Examiner rejected claims 58-61 under 35 U.S.C. § 103(a) as allegedly obvious over Ludwig et al. (US 2003/0082148) in view of Stickel et al. (1988) *J. Cell Biology* 107:1231-1239 and further in view of Kubo et al. (2000) *J. Oncology* 17:309-315.

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claim 58 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claims 59-61 depend from claim 58 and incorporate the features of this claim.

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle as recited in the pending claims. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

F. The Examiner rejected claims 62, 63 and 65 under 35 U.S.C. § 103(a) as allegedly unpatentable over Ludwig et al. (US 2003/0082148) in view of Handy et al. (US 2003/0032995).

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claim 62 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claims 63 and 65 depend from claim 62 and incorporate the features of this claim.

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle as recited in the pending

claims. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

G. The Examiner rejected claim 64 under 35 U.S.C. § 103(a) as allegedly unpatentable over Ludwig et al. (US 2003/0082148) in view of Handy et al. (US 2003/0032995) and further in view of Stickel et al. (1988) *J. Cell Biology* 107:1231-1239.

Applicant respectfully traverses the rejection. Without conceding the correctness of the rejection, and solely in the interest of expediting prosecution, Applicant has amended claim 62 to recite that the magnetic particles are coated with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle. Claim 64 depends from claim 62 and incorporates the features of this claim.

The cited references do not teach or suggest coating a magnetic particle with a peptide at a ratio of from 3 ng to 6.6 µg of the peptide to 1 mg of the magnetic particle as recited in the pending claims. The now-cancelled dependent claims 18, 22, 27, 32 and 48 previously recited this limitation and the Examiner did not reject them in this rejection. Therefore, for at least the foregoing reasons, the combined disclosure of the cited references does not render obvious the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. T0509.70012US00 from which the undersigned is authorized to draw.

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Respectfully submitted,

By 

Michael T. Siekman

Registration No.: 36,276

WOLF, GREENFIELD & SACKS, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

617.646.8000